

## **REMARKS**

### **I. Amendments to the Claims**

Currently, claims 4-8, 12-14, 16, and 37-52 are pending in the application with claims 4, 12, 16, 46, and 47 being the independent claims. Claims 9-11 and 18-36 were withdrawn, as being directed to a non-elected invention. Claims 4-5, 12, and 16 have been amended, and new claims 37-52 have been added. Claims 15 and 17 and withdrawn claims 9-11 and 18-36 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application.

Support for the amendments to claims 4-8, 12, and 16 and for new claims 37-52 can be found throughout the specification and claims as originally filed, particularly on pages 8-16 and 20-27 and throughout the concurrently filed Preliminary Amendment, particularly in Example 7. The amendments to claims 6-8 have been made solely in the interest of providing an antecedent basis for these claims with respect to the amendments to the language of base claim 4.

Additional support for the amendments to claims 4, 12, and 16 and for new claims 46 and 47 can be found, e.g., on page 8, lines 3-22; from page 9, line 4, to page 12, line 14; from page 15, line 9, to page 16, line 6; and in the Examples. Additional support for the amendments to claims 4-8 and for new claims 37-52 can be found, e.g., on page 7, lines 4-6; on page 9, lines 9-16; and in the claims as originally filed. Additional support for the amendments to claim 16 and for new claims 46 and 47 can be found, e.g., from page 9, line 19, to page 10, line 22; and in the Examples. Additional support for the amendments to claims 4, 12, and 16 and for new claims 45-47 and 52 can be found, e.g., from page 12, line 27, to page 13, line 6; from page 18, line 25, to page 19, line 28; and in the Examples. Additional support for the amendments to claim 16 and for new claims 37-44 and 46-51 can

be found, e.g., from page 8, line 3, to page 9, line 22; from page 10, line 16, to page 12, line 14; on page 14, lines 19-23; from page 15, line 9, to page 16, line 6; on page 19, lines 17-19; and in the Examples.

## **II. Status of the Claims**

Claims 1-36 were previously in the application. Claims 4-8 and 12-17 were elected in response to the Restriction Requirement. Claims 9-11 and 18-36 were withdrawn as being directed to a non-elected invention.

Currently, claims 4-8, 12-14, 16, and 37-52 are pending in the application with claims 4, 12, 16, 46, and 47 being the independent claims. Claims 4-8, 12, and 16 have been amended, and new claims 37-52 have been added. Claims 15 and 17 and withdrawn claims 9-11 and 18-36 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application.

## **III. The Rejection of Claims 9-11 and 18-36 is Traversed**

The Office Action Summary lists withdrawn claims 9-11 and 18-36 as rejected in addition to being withdrawn. Applicants respectfully traverse the rejection of these withdrawn claims, which were not elected.

## **IV. The Information Disclosure Statements Have Been Acknowledged**

Applicants thank the Examiner for acknowledging the Information Disclosure Statements mailed September 30, 2003, and September 24, 2004.

**V. Acknowledgement of the Priority Claim is Requested**

This application is a continuation application of U.S. Patent Application 09/736,659, filed 14 December 2000, which is a continuation-in-part of PCT application No. PCT/US00/10230, filed April 14, 2000, which claims the benefit of priority under 35 USC Section 119(e) of U.S. Provisional Patent Application No. 60/129,191, filed on April 14, 1999; U.S. Provisional Patent Application No. 60/180,353, filed on February 4, 2000; and U.S. Provisional Patent Application No. 60/193,556, filed on March 31, 2000, all of which are incorporated herein by reference. Applicants respectfully request acknowledgement of the priority claim accordingly.

**VI. The Rejection of Claim 5 under 35 U.S.C. §112, Second Paragraph, is Accommodated**

The Examiner has rejected claim 5 under 35 U.S.C. §112, second paragraph, for lack of antecedent basis for the phrase "said indicator means." Applicants have accommodated the Examiner and amended the claim to read "said indicator" in accordance with the Examiner's instructions.

**VII. The Rejection of Claims 4-8 and 12-17 under 35 U.S.C. §102(b) over Bloch is Traversed in Part and Rendered Moot in Part**

The Examiner has rejected claims 4-8 and 12-17 under 35 U.S.C. §102(b), alleging anticipation by Bloch et al. (U.S. Patent 4,789,630; filed 08/20/1986; issued 12/06/1988). Applicants respectfully disagree.

Claims 15 and 17 have been canceled without prejudice, and the rejection is moot with respect to these claims.

With respect to claims 4-5, 12, and 16-17, the Patent Office alleges:

Regarding claims 4 and 5, Bloch teaches a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon (col. 17, lines 63-64); a coating, wherein the coating comprises an anionic surfactant or detergent capable of cellular lysis (col. 14, lines 8-14 and 56-64); and an indicator for indicating the presence of nucleic acid, which is maintained on the solid support, wherein said indicator is a color indicator or fluorescent indicator (col. 31, lines 9-18; see also, col. 23, lines 39-47 and col. 11, lines 28-30).

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Regarding claim 12, Bloch teaches a kit comprising a dry substrate consisting: a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon (col. 17, lines 63-64); a coating, wherein the coating comprises an anionic surfactant or detergent capable of cellular lysis (col. 14, lines 8-14 and 56-64); and an indicator for indicating the presence of nucleic acid, which is maintained on the solid support, wherein said indicator is a color indicator or fluorescent indicator (col. 31, lines 9-18; see also, col. 23, lines 39-47 and col. 11, lines 28-30) and integrity maintenance means (col. 35, line 68 to col. 36, line 1).

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Regarding claims 16 and 17, Bloch teaches a card (sheet or paper) comprising a matrix, coating, an integrity maintenance means and indicator means, said card can further comprises blood (col. 17, lines 52-57; col. 18, lines 3-6; col. 23, lines 39-56). [Pp. 4-5; par. 5.]

Applicants respectfully disagree even without the present amendments. As currently amended, however, independent claims 4, 12, and 16 read as follows:

4 (currently amended). A kit for indicating the presence of nucleic acid in a sample, the kit comprising:

- a. a dry substrate for lysing cells and purifying nucleic acid therefrom consisting of:

- i. a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon; and
  - ii. a coating functionally associated with the solid matrix, wherein the coating comprises an anionic surfactant or detergent which facilitates cellular lysis; and
- a. an indicator for detecting the presence of nucleic acid, which is maintained on the solid matrix.

12 (currently amended). A kit for purifying nucleic acid comprising:

- a. a dry substrate comprising:
  - i. a solid matrix, wherein the solid matrix comprises nitrocellulose or nylon; and
  - ii. a coating functionally associated with the solid matrix, wherein the coating comprises an anionic surfactant or detergent which facilitates cellular lysis;
- b. an indicator for detecting the presence of nucleic acid, which is maintained on the solid substrate; and
- c. an integrity maintenance means for preserving the matrix and purifying nucleic acid.

16 (currently amended). A blood card for labeling blood transfusion bags comprising:

- a. a dry substrate comprising a solid matrix selected from the group consisting of nitrocellulose, carboxymethylcellulose, polyester, polyamide, polytetrafluoroethylene and porous ceramics, wherein the solid matrix further comprises a chemical coating functionally associated with the solid matrix, the chemical coating comprising:
  - i. a weak base;
  - ii. a chelating agent; and
  - iii. an anionic surfactant or detergent which facilitates cellular lysis; and
- b. an indicator for detecting the presence of nucleic acid, which is maintained on the solid matrix; and
- c. an integrity maintenance means.

Applicants respectfully submit that the Patent Office seems to be equating Southern blotting, dot blotting, and similar techniques with the dry solid medium of the claims, but in the present invention the chemical coating is already sorbed to the matrix to result in a dry solid medium, while Southern blotting and similar techniques apply purified DNA in an anion surfactant solution to a solid membrane surface for the detection of specific areas of the DNA.

Here, claims 4, 12, and 16 and the claims dependent thereon, are directed to a **dry** substrate, the **dry** substrate comprising a solid matrix **and** a coating **functionally associated with** the solid matrix which **facilitates cellular lysis**. The cells, blood, or other biological sample are brought into contact with the dry substrate, which itself facilitates cellular lysis. The nucleic acid is maintained on the solid matrix, where it is detected.

Moreover, the anionic surfactants of Bloch are directed toward facilitating use of the dye ion, rather than lysing the cells, and to the detection of DNA, for example, as part of a dot blot of previously isolated DNA or a blot of cells which are subsequently lysed by wetting with a separate lysis buffer, or after the DNA has been run on a gel.

Finally, the integrity device described by **Bloch** is **intended to keep the membrane wet and prevent it from drying out**:

The washed membrane was **stored in water** in a sealed test tube or plastic bag in the dark at room temperature, 4°C, or -20°C. [Col. 35, l. 68 – col. 36, l. 1; all emphasis added.]

In contrast, the integrity maintenances means (e.g., a plastic bag) of **the present invention has the exact opposite purpose** – namely, **to keep the membrane dry** to stop bacterial or fungal growth. While the specification mentions one embodiment having an air tight seal (e.g., pages 13-14), it is clear that the concern here is with prevention of bacterial contamination. Exposure to air can bring moisture with it.

Claims 5-8 are dependent on claim 4, claims 13-14 are dependent on claim 12, and the same arguments apply to these claims as well, thereby rendering moot the remaining arguments alleged by the Patent Office.

As a result of the foregoing, Applicant respectfully submits that the present claims 4-8, 12-14, and 16 fulfill the requirements of 35 U.S.C. §102(b) and requests the Examiner's reconsideration of these claims accordingly.

**VIII. The Rejection of Claims 4-8 and 15-17 under 35 U.S.C. §102(b) over Burgoyne is Traversed in Part and Rendered Moot in Part**

The Examiner has rejected claims 4-8 and 15-17 under 35 U.S.C. §102(b), alleging anticipation by Burgoyne (U.S. Patent 5,496,562; filed 11/30/93; issued 03/05/96). Applicants respectfully disagree.

Claims 15 and 17 have been canceled without prejudice, and the rejection is moot with respect to these claims.

The Patent Office alleges:

...Regarding claims 4 and 5, Burgoyne teaches a dry substrate consisting of a solid matrix comprises a cellulose-based paper (nitrocellulose) (col. 2, lines 21-25); a coating, wherein the coating comprises an anionic surfactant or detergent (col. 2, lines 59-64) and an indicator, which is maintained on the solid matrix, wherein the indicator is a color indicator (ink stamp or pencil marking) (col. 8-15).

Regarding claim 6, Burgoyne teaches wherein said substrate is a sheet (filter) or card (col. 2, lines 21-23 and col. 4, lines 61-65).

Regarding claim 7, Burgoyne teaches wherein the substrate further includes an integrity maintenance means (col. 3, lines 1-6).

Regarding claim 8, Burgoyne teaches wherein said substrate is a sheet (filter) and said integrity maintenance means is a plastic bag (plastic encasing) (col. 3, lines 1-6).

Regarding claims 15 and 16, Burgoyne teaches a substrate or blood card consisting of a matrix, a coating and integrity maintenance means (Col. 2, lines col. 47-64; col. 3, lines 1-6 and Example 2).

Regarding claim 17, Burgoyne teaches wherein the blood card further includes an indicator means for indicating the presence of nucleic acid (col. 5,

line 8-15). Therefore, Burgoyne meets the limitations of the claims of the instant invention. [P. 6, par. 6; footnote omitted.]

Applicants respectfully request clarification with the rejections regarding the integrity maintenance means at col. 3, lines 1-6 of Burgoyne.

Otherwise, Applicants respectfully disagree with the rejections. For example, the ink stamp or pencil marking of Burgoyne is not an indicator for detecting or quantifying the presence of nucleic acid on the card. Rather, the ink stamp or pencil marking of Burgoyne is simply a label and is not involved in the detection of nucleic acid on the card.

Claims 5-8 are dependent on claim 4, and the same arguments apply to these claims as well, thereby rendering moot the remaining arguments alleged by the Patent Office.

As a result of the foregoing, Applicant respectfully submits that the present claims 4-8 and 16 fulfill the requirements of 35 U.S.C. §102(b) and requests the Examiner's reconsideration of these claims accordingly.



### CONCLUSION

In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

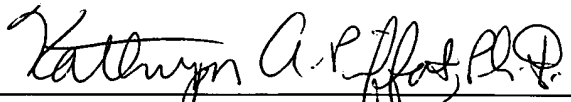
It is believed that all outstanding rejections have been addressed by this submission and that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

Applicants hereby request a two-month extension of time. If, however, a request for an additional extension of time is required, the Examiner is respectfully requested to treat this as a conditional request for an additional extension of time. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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